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John

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/050,614	03/30/98	BROWN	R F-5231

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EXAMINER

FLEMING, M

ART UNIT

PAPER NUMBER

1723

10

DATE MAILED: 08/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/050,614

Applicant(s)

Brown et al

Examiner

Michael A. Fleming

Group Art Unit

1723

☒ Responsive to communication(s) filed on Apr 14, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1, 2, 4-20, 22, and 23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 4-20, 22, and 23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☒ The proposed drawing correction, filed on Feb 10, 2000 is ☒ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-6, 11-17, 19-20, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroendorfer (US 4,445,883).

Schroendorfer discloses a processing assembly for insertion into and removal from an arcuate channel defined between inner and outer walls (Figure 5) which are rotated about a rotational axis comprising an elongated processing container 8 occupying the arcuate channel to convey fluids within the arcuate channel in a circumferential path about the rotation axis and a carrier 10 secured to the procession container shaped to maintain the processing container outside the arcuate channel in a rounded, flexed condition conforming to the arcuate channel. The carrier also limits deformation of the processing container during insertion into or removal from the arcuate channel. **(Instant Claim 1)**

Schroendorfer discloses a processing assembly comprising an arcuate centrifugal channel **(Figure 4)** defined between inner and outer walls which are rotated about a rotational axis, an elongated processing container 8 having flexibility and occupies the arcuate centrifuge channel to

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convey fluids within the arcuate centrifuge channel in a circumferential path about the rotation axis and a carrier **10** secured to the processing container shaped to maintain the processing container outside the arcuate channel in a rounded, flexed condition conforming to the arcuate centrifuge channel. The carrier also limits deformation of the processing container during insertion into or removal from the arcuate channel. **(Instant Claim 2)**

The carrier is adapted to assume a generally lay-flat configuration in the absence of external force **(Figure 3)**. **(Instant Claim 4)**

The carrier is pre-shaped. **(Instant Claim 5)**

The carrier is molded to retain the processing container in a flexed condition **(Figure 5)**. **(Instant Claim 6)**

The carrier comprises plastic material **(column 5, lines 60-64)**. **(Instant Claim 11)**

The processing container is secured to the carrier **(Figure 4)**. **(Instant Claim 12)**

The carrier includes first and second facing surfaces and an intermediate slot **(column 5, lines 64-67)**. **(Instant Claim 13)**

The carrier includes a surface contour which defines a wall contour **(Figure 4)**. **(Instant Claim 14)**

The carrier includes a surface projection which defines a wall projection the processing container **(Figure 3)**. **(Instant Claim 15)**

The processing container has a normal geometry when not secured to the carrier **(Figure 1)**. **(Instant Claim 16)**

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The assembly includes an umbilicus 20. **(Instant Claim 17)**

Schroendorfer discloses a blood processing assembly comprising an arcuate centrifugal channel defined between inner and outer walls which are rotated about a rotational axis (**Figure 4**), an elongated processing container 8 having a flexibility and which occupies the arcuate centrifuge channel, tubing 20 including a umbilicus (**Instant Claim 20**) integrally connected to the processing container to convey blood from a source into the processing container to convey fluids within the arcuate centrifuge channel in a circumferential path about the rotation axis, and a carrier 10 secured to the processing container shaped to maintain the processing container outside the arcuate centrifuge channel in a rounded, flexed condition conforming to the arcuate centrifuge. The carrier also limits deformation of the processing container during insertion into or removal from the arcuate channel. **(Instant Claim 19).**

Schroendorfer discloses a method of manufacturing an elongated, generally flexible blood processing container which is inserted or removed from an arcuate centrifugation channel comprising the step of attaching a carrier to shape the blood processing container outside the arcuate centrifuge channel in a rounded, flexed condition conforming to the arcuate centrifugation channel, the carrier serving to resist deformation of the processing container during insertion into and removal from the arcuate centrifugation channel. The blood processing container also serves to convey blood in a circumferential path within the arcuate centrifugation channel while the arcuate centrifugation channel is rotated about a rotational axis (**Figure 4**). **(Instant Claim 22)**

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Schroendorfer discloses a method of processing blood in an elongated generally flexible processing container occupying an arcuate centrifugation channel comprising the steps of attaching a carrier to shape a blood processing container outside of the arcuate centrifugation channel in a rounded, flexed condition conforming to the arcuate centrifugation channel, inserting the blood processing container into the arcuate centrifugation channel while shaped by the carrier, and performing a blood processing procedure (**Figure 4**) by conveying blood into the blood processing channel for flow in a circumferential path within the arcuate centrifugation channel while the arcuate centrifugation channel is rotated about a rotational axis. The carrier also serves to resist deformation of the processing container. (**Instant Claim 23**)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 7-10, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroendorfer in view of Mitchell et al (US 3,674,197).

Schroendorfer has been expanded. **(Instant Claim 1)**

Claim 7 adds the further limitation of the carrier being thermally formed to retain the processing container in the flexed condition.

Claim 8 adds the further limitation of the carrier being vacuum formed to retain the processing container in the flexed condition.

Mitchell teaches a carrier 11,12 for a processing container that may be injection molded or otherwise formed **(column 2, lines 31-40)**.

It would have been obvious to one having ordinary skill in the art at the same time the invention was made to incorporate different ways of making the carrier, as taught by Mitchell, to produce a carrier having certain properties. **(Instant Claims 7-8)**

Claim 9 adds the further limitation of the carrier comprising paper material.

Claim 10 adds the further limitation of the carrier comprising card board material.

Claim 18 adds the further limitation of the carrier includes a lubricious material.

Mitchell teaches a carrier 11,12 for a processing container that may comprise any suitable material **(column 2, lines 31-40)**. **(Instant Claims 9-10)**

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It would have been obvious to one having ordinary skill in the art at the same time the invention was made to incorporate different materials in making the carrier, as taught by Mitchell, to produce a carrier having certain properties. (**Instant Claims 9-10, 18**)

Response to Arguments

6. Applicant's arguments filed 4/4/00 have been fully considered but they are not persuasive.

In response to Applicant's argument that Schroendorfer fails to teach or suggest shaping an elongated processing container into a rounded flexed condition by securement to a carrier for insertion or removal as a unit into an arcuate separation channel, to convey fluid in a circumferential path about a rotational axis, several matters should be noted.

It should be noted that the processing container of Schroendorfer is indeed elongated (Figure 1).

It should be noted that the arcuate centrifugation channel of Schroendorfer is indeed annular and therefore arcuate (Figure 4).

It should be noted that inherently the processing container and the carrier of Schroendorfer must be shaped into a rounded, flexed condition for insertion and removal as a unit from the arcuate centrifugation channel. Otherwise, insertion or removal would be not impossible.

It should also be noted that by means for rotation, the fluid in the procession contained is conveyed in a circumferential path about a rotational axis.

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Fleming whose telephone number is (703) 305-0748. The examiner can normally be reached on Monday-Thursday from approximately 9:30 AM - 6:00 PM and on Friday from approximately 9:30 AM - 1:00 PM and 3:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. L. Walker, can be reached on (703) 308-0457.

The fax phone number for **Unofficial** faxes (i.e. faxes not to be entered, drafts) for Technology Center 1700 is **(703) 305-3602**. The fax number for **Official** faxes (i.e. faxes to become part of the file history) for this Center is **(703) 305-3599**. When filing a fax in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

MAF

M. A. Fleming

August 1, 2000

M. Savage

MATTHEW O. SAVAGE
PRIMARY EXAMINER
GROUP 1300